



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0720]

International Conference on Harmonisation; E2B(R3) Electronic Transmission of Individual Case Safety Reports; Draft Guidance on Implementation; Data Elements and Message Specification; Appendix on Backwards and Forwards Compatibility; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of Thursday, October 20, 2011 (76 FR 65199). The document announced the availability of a draft guidance entitled "E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs): Implementation Guide--Data Elements and Message Specification" (the draft E2B(R3) implementation guidance) and an appendix to the draft guidance entitled "ICSRs: Appendix to the Implementation Guide--Backwards and Forwards Compatibility" (the draft BFC appendix). The document was published with an incorrect date in the DATES section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: In FR Doc. 2011-27147, appearing on page 65199 in the Federal Register of Thursday, October 20, 2011, the following correction is made:

1. On page 65199, in the first column, in the DATES section, the date "January 18, 2011" is corrected to read "January 18, 2012".

Dated: November 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-29485 Filed 11/15/2011 at 8:45 am; Publication Date: 11/16/2011]